4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Immune Responses to Enzyme Replacement Therapies: Role of Immune Tolerance Induction; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cosponsorship with the National Organization for Rare Disorders (NORD), is announcing a 1-day public workshop entitled "Immune Responses to Enzyme Replacement Therapies: Role of Immune Tolerance Induction." Partners and stakeholders planning the workshop also include representatives from academia, industry, and patients. The purpose of this workshop is to provide a forum to discuss the role of immune tolerance induction in patients receiving replacement biological products.

DATES: The public workshop will be held on June 9, 2014, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm.1503), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Bldg. 1 where routine security check procedures will be performed. For parking and security information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Maureen Dewey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-0845, FAX: 301-796-9905, Maureen.Dewey@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA's Center for Drug Evaluation and Research, in co-sponsorship with NORD, is announcing a 1-day public workshop entitled "Immune Responses to Enzyme Replacement Therapies: Role of Immune Tolerance Induction." The cosponsored workshop will facilitate an ongoing dialogue among relevant parties on issues related to the role of immune tolerance induction in enzyme replacement therapies. The workshop will discuss the impact of anti-drug and neutralizing antibodies on efficacy and safety of enzyme replacement therapies intended to treat patients with lysosomal storage diseases and the risks and benefits of implementing prophylactic immune tolerance regimens to preclude generation of these antibodies. Stakeholders, including patients and patient organizations, industry sponsors, academia, and FDA, will discuss challenging issues related to immune tolerance induction in enzyme replacement therapies.

Registration: There is no fee to attend the public workshop, but advanced online registration is requested. Space is limited, and registration will be on a first-come, first-served basis. To register online, please visit https://events.rarediseases.org/?page_id=4&ee=13. Onsite registration the day of the workshop will be available, but advanced registration is preferred.

If you need special accommodations due to a disability, please contact Maureen Dewey (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Transcripts: Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and at http://www.regulations.gov approximately 30 days after the

workshop. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301-827-9267.

Dated: May 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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